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(पहला पुनरीक्षण)

Sterilized and Ultra High Temperature Sterilized Milk — Specification

(First Revision)

ICS 67.100.10

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भारतीय मानक ब्यूरो
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June 2020 **Price Group 5**

Dairy Products and Equipment Sectional Committee, FAD 19

FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Dairy Products and Equipment Sectional Committee had been approved by the Food and Agriculture Division Council.

Sterilization and Ultra High Temperature (UHT) sterilization of milk makes it free from viable bacteria and preserves it in a sterilized container for consumption as fluid milk for a long period which may be even six months. This standard is being prepared to help in controlling the quality and also as for guiding others to take up the production of sterilized/UHT sterilized milk.

For preparing sterilized/UHT sterilized milk, raw milk is tested for quality and clarified or filtered to eliminate particles of dirt, dust, etc. The milk may then be homogenized at a suitable pressure and temperature. The product is then filled in clean bottles or cans or aseptic packaging. It should, therefore, be free from harmful micro-organisms and toxins, and should not show signs of bacterial growth during storage.

This standard was originally published in 1967 and this first revision is being carried out to include the UHT sterilized/treated milk in its scope, to align the Indian Standard with the relevant FSSAI regulations and to introduce quality and safety characteristics for both raw milk and sterilized /UHT sterilized milk in the specification.

In the formulation of this standard, due consideration has been given to the *Food Safety and Standards Act*, 2006 and Regulations framed thereunder; the *Legal Metrology Act*, 2009 and Rules framed thereunder. However, this standard is subject to restrictions imposed under these, wherever applicable.

The composition of the Committee responsible for the formulation of this standard is given in Annex G.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 1960 ‘Rules for rounding-off numerical values (*revised*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

STERILIZED AND ULTRA HIGH TEMPERATURE STERILIZED MILK — SPECIFICATION

(First Revision)

1 SCOPE

This standard prescribes the requirements, sampling and methods of test for sterilized and Ultra High Temperature (UHT) sterilized milk.

2 REFERENCES

The following standards contain provision which through reference in this text, constitute provision of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below:

IS No./ International Standard	*Title*
1165 : 2002	Milk powder *(fifth revision)*
1223 : 2001	Apparatus for determination of milk fat by Gerber method — Specification (*third revision*)
1224 (Part 1) : 1977	Determination of fat by Gerber method: Part 1 Milk (*first revision*)
1479	Methods of test for dairy industry :
(Part 1) : 2016	Rapid examination of milk (*first revision*)
(Part 3):1977	Bacteriological analysis of milk (*first revision*)
2491 : 2013	Food hygiene — General principles — Code of practice (*third revision*)
4251 : 1967	Quality tolerances for water for processed food industry
3382 : 1965	Specification for stainless steel milk pipes and fittings
5253 : 1969	Guidelines for cleaning and sterilizing dairy equipment
5567:1970	Specification for bottles for sterilized milk
7768 : 1975	Sensory evaluation of milk
10500 : 2012	Drinking water — Specification (*second revision*)
11124 : 1984	Method for atomic absorption spectrophotometric determination of arsenic
11546 : 2012	Milk and milk products — Guidance on sampling *(second revision)*
12074 : 1987	Method for determination of lead by atomic absorption spectrophotometry
13334	Skimmed milk powder :
(Part 1) : 2014	Standard grade *(second revision)*
(Part 2) : 2014	Extra grade *(first revision)*
IS 13688 : 2020	Packaged pasteurized milk — Specification (*second revision*)
13689 : 1992	Butter oil (butter fat)
13690 : 1992	Pasteurized butter
ISO 14501: 2007	Milk and milk powder — Determination of aflatoxin M1 content — Clean-up by immune affinity chromatography and determination by high-performance liquid chromatography

3 DEFINITIONS

3.1 Milk

Milk is the normal mammary secretion derived from complete milking of healthy milch animal without either addition of thereto or extraction therefrom, unless otherwise specified. It shall be free from colostrum. Milk which is adjusted for milk fat or milk solid-not-fat content or both, may also be named "milk" provided that the limits of milk fat and milk solid-not-fat content of the adjusted milk conform to the specific type of milk as applicable (*see* **4**).

3.1.1 *Recombined Milk*

Recombined milk is a product resulting from the combination of milk fat and milk-solids-non-fat in their preserved forms with or without the addition of potable water to achieve similar end product characteristics and appropriate milk composition as per the standard for the specific type of milk. The source of milk-solids-non-fat shall be dried or concentrated milks only.

3.1.2 *Reconstituted Milk*

Reconstituted milk is a product resulting from the addition of potable water to the dried or concentrated form of milk in the amount necessary to re-establish the appropriate water-to-solids ratio to achieve similar end product characteristics and appropriate milk composition as per the standard for the specific type of milk for that product.

3.2 Sterilisation

Sterilisation, sterilized and similar terms, when used in association with milk or milk products, shall be taken to refer to the process of heating milk or milk product in sealed container continuously to at least 115ºC for fifteen minutes or equivalent heat treatment to ensure preservation at room temperature for a period not less than 30 days from the date of manufacture.

3.3 Ultra High Temperature (UHT) Sterilization

Ultra high temperature (UHT) sterilization, ultra high temperature (UHT) treatment or ultrahigh temperature sterilized or similar terms**,** when used in association with milk or milk product, shall be taken to refer to the process of heating milk or milk product to at least 135ºC for a period of one second or more in a continuous flow and then packing under aseptic condition in hermetically sealed containers to ensure preservation at room temperature for a period not less than 30 days from the date of manufacture.

4 TYPES

The sterilized milk and UHT sterilized milk may be prepared from any of the types of milk as defined in IS 13688.

5 REQUIREMENTS

5.1 Raw Milk Quality

Milk intended for sterilization / UHT sterilizing shall be wholesome and shall be free from any added extraneous matter. It shall be tested for its freedom from preservatives, neutralizers, adulterants [*see* IS 1479 (Part 1)]. Milk shall also be evaluated for organoleptic requirements (*see* IS 7768), temperature, acidity, bacterial load, so that these parameters can serve as guidelines to the processors for continual improvement in the quality. Milk with methylene blue reduction (MBRT) time of not less than 120 min and with a negative alcohol test shall be accepted for processing. The MBRT test shall be conducted as per IS 1479 (Part 1) and results interpreted as per IS 1479 (Part 3). The alcohol test shall be conducted as per IS 1479 (Part 1).

5.2 Ingredients

Dairy based ingredients like concentrated milk, whole milk powder (conforming to IS 1165), skimmed milk powder [conforming to IS 13334 (Part 1) or IS I3334 (Part 2)], butter (conforming to IS 13690) and butter oil (conforming to IS 13689) may be used. Other non-dairy ingredients like potable water shall conform to IS 10500. However, water used for steam generation for use in direct injection steam plant shall conform to IS 4251.

5.3 Hygienic Requirements

Milk shall be processed, sterilized, packed and handled under strict hygienic conditions as prescribed in IS 2491.

5.3.1 *Milk Plant*

The building where the milk is received, processed, bottled or filled in other containers, stored and where the equipment and containers are cleaned and sterilized shall be such that it satisfies the requirements laid down in IS 2491. The floors, walls and ceilings, doors and windows, lighting arrangement, ventilation, toilet and hand washing facilities shall also comply with the requirement of IS 2491.

5.3.2 *Water Supply*

The water supply shall conform to the tolerances specified for water for dairies as per IS 4251 or IS 10500 as applicable and shall be easily accessible and adequate.

5.3.3 *Sanitary Piping*

All pipings and fittings which come in contact with milk shall be of sanitary types which can be easily cleaned and sanitized (*see* IS 3382).

5.3.4 *Equipment and Containers*

Milk receiving equipment, storage tanks, sterilizing and cooling equipment, cans, bottles, and other packing materials with which milk comes into contact shall be of smooth, impervious, noncorrosive, non-toxic material conforming to relevant Indian Standards, wherever available and so constructed as to be easily cleaned and sanitized.

5.3.5 *Cleaning and Sanitization of Plant Equipment and Containers*

The sterilizing plant and other equipment used for receiving, processing, storage and bottling, and milk cans, bottles and other packing material used for filling milk, shall be cleaned and sanitized (*see* IS 5253). After sanitization and during usage or storage, the equipment and containers shall be protected from contamination.

5.3.6 *Surroundings and Waste Disposal*

The immediate surroundings shall be kept neat and clean and proper arrangement made for the disposal of waste.

5.3.7 *Personnel Health and Cleanliness*

All employees and other persons handling milk or equipment in the plant shall be medically examined every six months by a competent authority and certified to be physically fit and free from infections or other communicable diseases. All persons working in the plant shall wear clean garments, preferably coats/ aprons and caps, and strictly adhere to rules of personal hygiene (*see* IS 2491).

5.4 General Process

Raw milk is tested for quality and clarified or filtered to eliminate particles of dirt, dust, etc. After standardizing for the minimum compositional requirements (if necessary) the milk shall be homogenized at a suitable pressure and temperature. Subsequently, specific process requirements shall be followed as given in **5.4.1** and **5.4.2**.

5.4.1 *Sterilized Milk*

The milk shall be filled in clean bottles or cans. The containers are capped or sealed air-tight and placed in a sterilizer (batch/continuous) where the containers are gradually heated to continuously to at least 115ºC for fifteen minutes or equivalent heat treatment to ensure preservation at room temperature for a period not less than 30 days from the date of manufacture. The containers are then gradually cooled either in a current of air or water.

5.4.2 *UHT Sterilized Milk*

The milk shall be heated to at least 135ºC for a period of one second or more in a continuous flow and cooled immediately and then packing under aseptic condition in hermetically sealed containers to ensure preservation at room temperature for a period not less than 30 days from the date of manufacture.

5.5 The product shall also comply with the requirements given in Table 1.

5.6 Keeping Quality

Sterilized and UHT milk shall have minimum shelf life of 30 days when stored in ambient conditions.

6 PACKING AND MARKING

6.1 Packing

Sterilized milk shall be packed in clean, sound and sanitary glass bottles (*see* IS 5567) or bottles made of polypropylene conforming to IS 10910 or Poly ethylene terephthalate conforming to IS 12252 or cans properly sterilized and stored in such a way as to protect it from contamination and deterioration. UHT sterilized milk shall be packed under aseptic condition in a sterile package and hermetically sealed so as to retain the quality attributes and prevent ingress of external agents (air/water/microbes/particulate matter etc.) as long as the structural and seal integrity are maintained. The packing material shall retain the required aseptic conditions throughout the storage duration.

Table 1 Requirements for Sterilized / UHT Sterilized Milk

(*Clause* 5.5)

Sl No.	Characteristics	Requirement	Method of Test (Ref to Annex)
(1)	(2)	(3)	(4)
i)	Creaming index, *Max.*	10	A
ii)	*Nizo* index	*Min* 90 percent	B
iii)	Turbidity	To confirm to test	C
iv)	Sterility		
	*p*H variation on 7 days incubation, *Max.*	0.3	D
	or	0.02	E
	Titratable acidity (variation on 7 days incubation), percent, *Max.*		
v)	Bacterial spores per ml, colonies, *Max.*	Absent	F
vi)	Lead, *Max*	0.02 ppm	IS 12074
vii)	Arsenic, *Max*	0.1 ppm	IS 11124
viii)	Aflatoxin M_{1}, *Max*	0.5 ppb	ISO 14501

NOTES:

1 Approved and validated international test methods from ISO/ IDF/EN/APHA/ ASTM/ AOAC/ EPA may also be followed.

2 In case of dispute, methods given at column 4 shall be the referee method.

6.2 Marking

6.2.1 The following information shall be marked legibly and indelibly on each container/packet:

a) Name of the material 'Sterilized / UHT Sterilized milk';
b) Type of milk as applicable;
c) Batch or code number;
d) Date of packing and/or time;
e) Name of the manufacturer or processor;
f) Net volume, in ml or litre;
g) Best before date /use by date;
h) Fat ------- percent, solid-not-fat ------ percent;
j) Storage conditions and temperature; and
k) Any other requirements under the *Food Safety and Standards (Packaging and Labelling) Regulations*, 2011 and the *Legal Metrology Act*, 2009 and Rules framed thereunder.

6.2.2 *BIS Certification Marking*

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

7 SAMPLING

Representative samples of sterilized and UHT milk shall be drawn, handled, stored and tested for conformity to this standard by the method prescribed in IS 11546.

ANNEX A

[*Table* 1, *Sl No*. (i)]

DETERMINATION OF CREAMING INDEX

A-1 GENERAL

Low creaming index is an indication of good homogenization. Sterilized and UHT sterilized milk may be graded as under for the quality of homogenization:

Quality of homogenization	Creaming Index
Excellent	Up to 10
Good	11 to 20
Fair	21 to 30
Poor	Over 30

A-2 APPARATUS

A-2.1 Glass Tubes, with ground glass stoppers, outside diameter 24 mm length with stoppers 245 mm (suitable for use with a 24 tube Gerber centrifuge), and graduated from 0 to 50 ml.

A-2.2 Pipette, fine pointed, connected to a suitable vessel and to a vacuum pump.

A-2.3 Apparatus for the Determination of Fat, as specified in IS 1223.

A-3 PROCEDURE

A-3.1 Place 50 ml of the material at 20±1°C in each of the three tubes. Centrifuge for 15 min at 1 000 rev/min.

A-3.2 Using separate pipette, take 5 ml from the upper part of each of the three tubes, carefully taking the cream that adheres to walls of the tube and transfer into a container (sample I). Then empty the three tubes into a separate container (sample II). Measure the fat content in the samples I and II by the Gerber method as described in IS 1224 (Part 1) taking all the precautions required to be taken for homogenized milk that is, heating the sample at 65±2°C for 5 min in a water-bath after each centrifuging before taking the reading till identical readings are obtained. Usually three centrifugings are required each lasting for at least 5 min.

A-4 CALCULATION

$$\text{Creaming index} = \frac{(A - B)}{B} \times 100$$

Where,

A = fat content of the sample I, and

B = fat content of the sample II.

ANNEX B

[*Table* 1, *Sl No*. (ii)]

DETERMINATION OF NIZO INDEX

B-1 GENERAL

This test is carried out for homogenized milk to check efficiency of homogenization. Higher *Nizo* index is an indication of good homogenization.

B-2 PROCEDURE

First check the fat content of milk sample. Take the 25 ml of sample in centrifuge tube at 40^0C. Centrifuge for 30 min at 2 000 rpm of radius 125 mm. Check the fat percent of milk from bottom of the tube. Fat percent of milk at the bottom divided by fat content of the whole milk sample and the ratio is multiplied by 100.

B-3 CALCULATION

$$\textit{Nizo}\text{ index} = \frac{\text{Fat \% of milk at the bottom}}{\text{Fat \% of the whole milk sample}} \times 100$$

ANNEX C

[*Table* 1, *Sl No*. (iii)]

DETERMINATION OF TURBIDITY

C-1 GENERAL

Turbidity test is performed to assess the severity of heat treatment rendered to milk during the process of in bottle sterilization. In bottle sterilization completely denatures whey proteins irreversibly which can be filtered out from milk by treating it with a suitable reagent.

C-2 APPARATUS

C-2.1 Water-Bath

C-2.2 Glass Test Tube, 16 x 160 mm size, perfectly transparent.

C-2.3 Erlenmeyer Flask, 50 ml capacity

C-2.4 Whatman No. 12 or its Equivalent Filter Paper, 12.5 cm diameter.

C-3 REAGENTS

C-3.1 Ammonium Sulphate

C-4 PROCEDURE

Place in a 50 ml Erlenmeyer flask 1 g of ammonium sulphate and 20 ± 0.5 ml of the sample at room temperature. Agitate the flask for about one minute until the ammonium sulphate dissolves. Let the solution stand for at least 5 min, then filter it through the pleated filter paper. Collect 5 ml of the filtrate in the glass test tube (**C-2.2**). Place the tube in a boiling water-bath. Examine the tube by moving it before a source of light from which the observers' eyes are screened. The filtrate should be clear.

C-5 INTERPRETATION

Even a slight turbidity would indicate an insufficient heat treatment given to the sterilized milk.

ANNEX D

[*Table* 1, *Sl No*. (iv)]

DETERMINATION OF *p*H

D-1 GENERAL

*p*H test is performed to assess the variation in *p*H levels during the incubation period. *p*H variation can be an indicator of microbial activity which may be leading to acid production. The determination of *p*H shall be done as per IS 1479 (Part 1).

D-2 INTERPRETATION OF RESULTS

Sample which does not show any physical alteration during incubation at 55±1 °C for 7 days and where the *p*H does not show a difference of more than 0.3 unit from the initial *p*H, is considered sterile.

ANNEX E

[Table 1, Sl No. (iv)]

DETERMINATION OF TITRATABLE ACIDITY

E-1 GENERAL

Titratable acidity test is performed to assess the variation in developed acidity levels during the incubation period. Excessive variation can be an indicator of microbial activity which may be leading to acid production. The determination of titratable acidity shall be done as per IS 1479 (Part 1).

E-2 INTERPRETATION OF RESULTS

Sample which does not show any physical alteration during incubation at 55 ± 1 °C for 7 days and where the acidity does not show a difference of more than 0.02 percent from the initial acidity is considered sterile.

ANNEX F

[*Table* 1, *Sl No*. (v)]

DETERMINATION OF TOTAL BACTERIAL SPORES

F-1 GENERAL

Low spore count in the finished product is essential to ensure a safe and stable sterilized/UHT sterilized milk.

F-2 APPARATUS

F-2.1 Dairy Bacteriological Pipettes, to deliver one millilitre of milk.

NOTES:

1 Use of improperly cleaned pipettes may cause incomplete deliveries of test portions. To facilitate removal of milk solids, preferably rinse the pipettes immediately after use with water. After rinsing thoroughly, wash the pipettes with suitable detergents (such as alkyl sulphonate type or an alkaline phosphate) and then rinse until all detergent residues are removed. Exercise caution when using wetting agents for glassware washing as some of these have been found to adhere tenaciously and result in inhibiting growth.

2 To ensure complete cleaning, soak the pipettes for 24 h at weekly intervals, in strong cleaning solution and rinse several times with clean water. A cleaning solution may be prepared by dissolving 50 g of sodium or potassium bichromate in 200 ml of water in a glass or glazed earthen container, and then by adding cautiously with stirring 300 ml commercial sulphuric acid.

3 Before use, test a few pieces of glassware in each batch for the presence of residual acid of alkali with appropriate indicator, such as bromothymol blue.

F-2.2 Pipette Container, preferable of metal, may be round, square or rectangular, length about 400 mm.

F-2.3 Petri Dishes, outside diameter 98 mm, inside diameter about 94 mm, depth 15 mm, with flat bottom and free from bubbles, scratches and other defects.

F-2.4 Petri Dish Containers, metal boxes with covers, cylindrical or square, for protection and convenient handling of dishes both before and after sterilization.

F-2.5 Hot Air Oven, capable of giving uniform and adequate temperatures, equipped with a thermometer calibrated to read up to 220 °C, and with vents suitably located to ensure prompt and uniform heating.

F-2.6 Autoclave, capable of providing uniform temperatures within the chamber up to the sterilizing temperature of 121 °C, equipped with accurate mercury filled thermometer with bulb properly located so as to register the minimum temperature within the sterilizing chamber (with or without temperature recording instrument), pressure gauge and properly adjusted safety valve.

F-2.7 Incubators, two, either water jacketed or anhydric type, electrically heated, thermostatically controlled and provided with shelves so spaced as to ensure uniformity of temperature, one maintained at 30 ±1°C and other 55 ±1°C.

F-2.8 Hand Tally, a mechanical counting device.

F-2.9 Potentiometer or Comparator with Standard Colour Discs, for accurate determination of *p*H of media.

F-2.10 Media Making Utensils, natural, heat resistant glassware or other suitable non corrosive equipment, clean and free from foreign residues or foreign material which may contaminate media, such as chlorine, copper, zinc, aluminium, antimony and chromium.

F-3 REAGENTS

F-3.1 Prepare the solid media by dissolving the following ingredients in 1 000 ml of distilled water.

	g
Trypton	10
Yeast extract	3
Glucose	1
Soluble starch	1
Agar, bacteriological grade	8

After dissolving the above ingredients, adjust the *p*H to 7. Place in each 200 × 20 mm tubes, about 20 ml of media. Sterilize in the autoclave for 15 min at 120°C (or 1 kg/cm^2 steam pressure). Media may be stored at 4°C for not more than one month.

F-3.2 Ready-made media may also be used.

F-4 PROCEDURE

F-4.1 Pouring Plates

Add aseptically one millilitre of the sample to petridishes. Melt the agar medium in the boiling water bath and cool to 45°C. Introduce 20 ml of the medium aseptically into the petridishes within 5 min and mix by rotating and tilting the dish without splashing over edge. Spread the mixture evenly over the bottom of the plate. Allow to solidify.

F-4.2 Incubation

Invert the dishes and incubate at 30 ±1 °C and 55 ±1 °C separately for 4 days in the incubator.

F-4.3 Counting

Count the colonies with aid of hand tally.

ANNEX C

(*Foreword*)

COMMITTEE COMPOSITION

Dairy Products and Equipments Sectional Committee, FAD 19

Organization	*Representative(s)*
National Dairy Research Institute, Karnal	Dr R. R. B. Singh, (***Chairman***)
National Dairy Research Institute, Karnal	Dr Vivek Sharma Dr Rajesh Kumar Bajaj (*Alternate*)
All India Food Processors Association, New Delhi	Dr K. L. Gaba Mr Vijay Gaur (*Alternate*)
Bihar State Cooperative Milk Producers' Federation Ltd (COMPFED), Delhi	Shri Sushil Kumar Shri Rupesh Raj (*Alternate*)
CONCERT, Chennai	Shri K. Ramachandran Mr M. R. Krishnan (*Alternate*)
Confederation of Indian Food Trade & Industry, New Delhi	Ms Priyanka Gupta Dr Anirudha Chhonkar (*Alternate*)
Confederation of Indian Industry, New Delhi	Ms Neha Aggarwal Ms Arti Gupta (*Alternate*)
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Export Inspection Council of India, New Delhi	Dr J. S. Reddy Mr Vikas Dahiya (*Alternate*)
FICCI Research and Analysis Centre, New Delhi	Dr S. K. Manocha Dr Ajay Sharma (*Alternate*)
Food Safety and Standards Authority of India, New Delhi	Dr Monica Puniya Ms Tripti Tayal(*Alternate*)
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Haryana Dairy Development Coop. Federation Ltd, Panchkula	Mr S. S. Kohli Shri Y. P. Singh (*Alternate*)
IDMC Ltd, Anand	Mr Rajesh Subramanian Shri Devender Gupta (*Alternate*)
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National Dairy Development Board, Anand	Dr D. K. Sharma Shri Narinder Sharma (*Alternate*)
National Institute of Nutrition, Hyderabad	Dr B. Santosh Kumar Shri Sylvia Fernandez Rao (*Alternate*)

Organization	*Representative(s)*
Pradeshik Co-op. Dairy Federation Ltd, Lucknow	Mrs Shabnam Chopra
Rajasthan Co-operative Dairy Federation (RCDF) Ltd, Jaipur	Shri J. D. Singh
The Tamil Nadu Co-operative Milk Producers' Federation Limited, Chennai	Mr S. R. Sankar Mr T. M. James Dinakaran (*Alternate*)
Infant and Young Child Nutrition Council,	Dr Nirupama Sharma Mr Kiran Desai (*Alternate*)
Centre for Analysis and Learning in Livestock and Food (CALF), Anand	Dr Rajesh Nair Dr Rajeev Chawla (*Alternate*)
M/s Punjab State Cooperative Milk Producers' Federation Limited.	Dr Brar
Vimta Labs Limited, Hyderabad	Dr Jagdish Kodali Dr Muni Nagendra Prasad Poola (*Alternate*)
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Member Secretary

Suneeti Toteja
Scientist 'E', (FAD), BIS

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